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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,426	12/10/2003	Paul O. Zamora	01173/100C071-US6	2146

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EXAMINER	
JONES, DAMERON LEVEST	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/733,426	ZAMORA ET AL.	
	Examiner	Art Unit	
	D. L. Jones	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the preliminary amendment filed 12/10/03 wherein the specification was amended; claims 1-19 were canceled; and claims 20-31 were added.

Note: Claims 20-31 are pending.

APPLICANT'S INVENTION

2. Applicant's invention is direct to a product (kit) comprising a protein, stannous ion, stabilizer (ascorbic acid and water soluble salts, esters, and mixtures thereof), and Tc-99m.

DOUBLE PATENTING REJECTION

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 20-23, 27, and 28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-23, 25, 28, and 29 of U.S. Patent No. 6,066,309. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compositions comprising a partially reduced protein (i.e., antibody), stannous ion, and stabilizer (ascorbic acid and water soluble salts, esters, and mixtures thereof). The claims differ in that the instant invention specifically states that the compositional product is a kit. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a kit since in the patented invention, for example, claim 2, it is disclosed that the composition of claim 1 is in the form of a lyophilized kit.

112 FIRST PARAGRAPH REJECTIONS

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 20, 21, and 24-31are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for kits wherein the partially reduced protein is an anti-SSEA-1 IgM monoclonal antibody, does not reasonably provide

enablement for all partially reduced protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to a it comprising a partially reduced radiolabeled protein, stannous ion, and stabilizer selected from ascorbic acid and water soluble salts, esters, and mixtures thereof.

(2) State of the prior art

The references do not indicate which specific partially reduced proteins are useful with the claimed invention.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. Independent claim 20 encompasses a vast number of possible proteins. Applicant's specification does not

enable the public to make or use such a vast number of possible partially reduced proteins.

(4) Level of predictability in the art

The art pertaining to proteins is highly unpredictable. Determining the various types of proteins or class of proteins that are encompassed by the instant invention requires various experimental procedures and without guidance that is applicable to all proteins, there would be little predictability in performing the claimed invention. Furthermore, it is noted that the definition of the term protein as sometimes used in the art encompasses proteins, polypeptides, peptides, and antibodies (see Srinivasan et al columns 3-4, bridging paragraph).

(5) Amount of direction and guidance provided by the inventor

Independent claim 20 encompasses a vast number of proteins. Applicant's limited guidance does not enable the public to prepare such a numerous amount of proteins. There is no directional guidance for the specific proteins. Hence, there is no enablement for all possible permutations and combinations of partially reduced proteins.

(6) Existence of working examples

Independent claim 20 encompasses a vast number of proteins. Applicant's limited working examples do not enable the public to prepare such a numerous amount of proteins. While Applicant's claims encompass a plethora of possible proteins, the specification provides only one partially reduced protein, anti-SSEA-1 IgM monoclonal antibody.

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible partially reduced proteins known to exist.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 SECOND PARAGRAPH REJECTIONS

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 20, 21, and 24-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims as written are ambiguous because one cannot readily ascertain what is being claimed. Specifically, the claims as written read on a multitude of possible proteins. However, one of ordinary skill in the art would not be able to ascertain what is encompassed in the claim as written since the definition of the term protein as often used in the art encompasses proteins, peptides, polypeptides, and antibodies.

Applicant is respectfully requested to clarify the claim in order that one may determine what is being claimed.

103 REJECTION

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 20, 21, and 24-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grogg et al (US Patent No. 4,510,125).

Grogg et al disclose compositions that are useful for making imaging kits (see entire document, especially, abstract). The kits comprise a tissue specific carrier and a stannous compound (abstract). In addition, the following ingredients may also be present in the composition, Tc-99m (column 3, lines 55-64); a stabilizer such as ascorbate compounds (i.e., ascorbic acid, erythrobic acid, and so forth) [column 5, lines 38-67; columns 12-13, bridging paragraph]; stannous ion (column 7, lines 4-6); and a tumor specific antibody (column 9, lines 1-3). The kit may be lyophilized (columns 10-11, bridging paragraph). The kit components may be in an aqueous solution of sterile, pyrogen-free water (column 10, lines 55-58). Also, additional components may be present. Possible components include, for example, disodium edentate (EDTA) [column 14, line 42]. Furthermore, Grogg et al disclose that it is not necessary that all the components of the kit be present in the same container(s) [column 6, lines 23-32;

column 9, lines 35-48; column 10, line 8 through column 11, line 47; columns 12-13, bridging paragraph]. While Grogg et al does not disclose a *specific* example having all the components as set forth by Applicant, the reference does disclose that kits having all the components necessary in Applicant's kit may be generated from their invention.

It would have been obvious to one of ordinary skill in the art at the time the invention was made generate a kit comprising a protein, stannous ion, stabilizer (ascorbic acid and water soluble salts, ester, and mixtures thereof) because Grogg et al disclose a kit comprising a composition encompassed by the instant invention. In particular, the composition may comprise Tc99m, stannous tartrate, and antibody, and ascorbic acid. Hence, both Applicant and Grogg et al are directed to kit compositions.

SPECIFICATION

11. The disclosure is objected to because of the following informalities: (1) the status of the cases in the continuing data needs to be updated; and (2) page 12 of the specification contains some markings on the page, thus, a readable copy (unmarked) is needed.

Appropriate correction is required.

COMMENTS/NOTES

12. It should be noted that no prior art has been cited for an anti-SSEA-1 IgM monoclonal antibody. However, Applicant must address and overcome the double patenting rejection over the claims. In particular, the claims wherein the protein is labeled with 99mTc and is an anti-SSEA-1 IgM monoclonal antibody are distinguished over the prior art of record because the prior art neither anticipates nor renders obvious

the protein in combination with stannous ion, and ascorbic acid and water soluble salt, esters, and mixtures thereof.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1616

July 20, 2004